Remarks and argument

Claims 1-5, 7, 11-12, 16-35, 37-39, 41-43, 45-46, 55-60, and 64-66 are pending in this application. Claims 1, 55 and 64 are independent. Claims 61-63 are withdrawn.

Applicant thanks the Examiner for pointing out the word processing error of the claim status in claim 43. This has been corrected. This correction is purely formal in nature and for this reason, Applicant respectfully submits that this subject amendment should not narrow the available scope of equivalents under the Doctrine of Equivalents.

The text of the canceled claims has been deleted.

Claims 61-63 are now withdrawn. Applicant did not withdraw these claims in the previous response because Applicant mistakenly believed that the need to withdraw them no longer existed because term "orally acceptable carriers" also included "restoratives, etc." had been fully explained to the Examiner during the interview, with reference to the specification, for example, paragraph [0039]. Applicant hereby reiterates that point and respectfully reserves the right to rejoin the claims when a generic claim encompassing "oral care" is indicated as allowable.

Claims 1 and 55 are amended. Support for the amendment is found throughout the specification, for example, paragraphs [0029], [0030], [0033] etc. No new matter is added.

The deletion of the pH range from claim 1 broadens and not narrows the claims. Thus, this subject amendment should not narrow the available scope of equivalents under the Doctrine of Equivalents.

Claims 64-66 are added. Support for these new claims is found throughout the specification, for example, paragraphs [0029], [0030], [0033], [0037], [0039] etc. No new matter is added.

Reconsideration is respectfully requested.

I. Rejection under 35 U.S.C. 103(a)

Claims 1-5, 7, 11, 12, 16-35, 37-39, 41-43, 45,46 and 55-60 are rejected under 35 U. S.C. 103(a) as being unpatentable over Show Denko KK JP 62096408 in view of Pera U.S. Patent No. 4,755,525 and Parran et al. U.S. Patent No. 4684518.

The claims are drawn to a composition comprising ascorbyl-2-phosphate or a sodium or potassium salt thereof and further comprising calcium ions wherein the composition is mixed with an orally acceptable carrier, and further comprising a calcium chelating agent, a pyrophosphate, tripolyphosphate or polyphosphate tartar control agent, a water soluble fluid, water soluble solid, humectant, thickener, surfactant, sweetener, flavorant, colorant, abrasive, stabilizer, fluoride containing compound, anticaries agent, antimicrobial agent, essential oil and a desensitizing agent.

Showa Denko KK teach ascorbic acid phosphoric acid ester or it's salt (e.g. Na^+, K^+, Ca^{++} or Mg^+ salt) in an oral composition to be used for alveolar pyorrhea, cleaning teeth, removing bad breath and washing the teeth. It is in compositions such as toothpaste, chewing gum and troches. Working example I teaches calcium diphosphate dihydrate (source of calcium/abrasive), sodium carboxymethylcellulose and carrageenan (thickeners), glycerin (water soluble liquid), sorbital (water soluble solid), fragrance (flavor), preservative (antimicrobial), sodium saccharin (sweetener), sodium lauryl sulfate (surfactant), and ascorbic acid magnesium phosphate.

Showa Denko does not teach the desensitizing agents of claims 40-44, it does not teach the non water-soluble solid and liquid and it does not teach the pyrophosphate, tripolyphosphate or polyphosphate tartar control agent.

Pera (4,755,525) teaches strontium desensitizing agent for the teeth (column 5, lines 27-43). It would have been made obvious to one of ordinary skill in art at the time it was made to incorporate desensitizing agents and vegetable oils and wax. Such a modification would have been motivated by the reasoned expectation of producing a dentifrice composition which is effective in comprehensively cleaning teeth and desensitizing teeth of individuals that have become sensitized. Strontium is a well-known desensitizer, which is known and used in dentifrices as evidenced by the teachings of Pera (4,775,525). Vegetable oil would aid in mixing the dentifrice composition and the wax would effectively coat the teeth and add shine to the teeth.

Parran et al. teach oral compositions containing pyrophosphate salts which provide an anticalculus (aka tartar) benefit (see abstract) and teach the pyrophosphates salts useful in the invention in an amount of about 1.5% (column 2, lines 28-52) which is encompassed by the claimed 1 % to about 4%.

It would have been made obvious to one of ordinary skill in art at the time it was made to incorporate the instantly recited tartar control agents. Such a modification would have been motivated by the reasoned expectation of producing a dentifrice composition, which is effective in comprehensively cleaning teeth and removing tartar. As stated in Parran et al., the pyrophosphate salts provide an anticalculus (tartar control) benefit in dentifrices (see abstract).

See http://pubs.acs.org/hotartcl/chemtech/95/dec/dec.html December 1 995 wherein it is recited that Sodium fluoride, sodium monofluorophosphate, and stannous fluoride are the most common fluoride sources used in toothpaste.

Great care must be taken in the formulation of these agents so that their anticaries activity is not reduced by other dentifrice ingredients, such as the abrasive system. For example, whereas sodium monofluorophosphate is compatible with both silica and dicalcium phosphate dihydrate abrasives, sodium fluoride is most compatible with the silica abrasive at neutral pH values. Thus it would have been obvious to employ a pH of 5.5 to 10 since this range encompasses neutral pH's and this would be most compatible for formulations with fluoride.

Applicant respectfully traverses the rejection. As this rejection is practically identical to the previous rejection, arguments have been presented both at the interview and in the response previously filed for the rejection. Part of it will not be reiterated here. Also, claims 1 and 55 are amended. The rejections are now also believed to be moot.

Showa Denko KK teaches ascorbic acid phosphoric acid ester or it's salt (e.g. Na^+, K^+ Ca^{++} or Mg^+ salt) in an oral composition to be used for alveolar pyorrhea, cleaning teeth, removing bad breath and washing the teeth. The oral composition is in the form of a toothpaste, a chewing gum and troches. However, since calcium diphosphate dehydrate is also taught as an abrasive, large amounts of the phosphate material is used, specifically 45%. (Emphasis added) There is no teaching of the present invention of claims 1 and 55, as previously submitted or as presently amended.

Pera U.S. Patent No. 4,775,525 is cited by the Examiner to show that a strontium compound can be a desensitizing agent. In addition, Applicant also likes to point out that Pera essentially teaches away from the use of normal tartar control agents and abrasives. "In general, while no abrasive is harsh enough to remove enamel, some dentifrices may harm cementum and dentin. These

products should be avoided by individuals with periodontal disease and hypersensitive teeth. Identifying the different kinds of offending dentifrices is difficult because the interaction of inert ingredients in each formula (which changes over time) may enhance or retard the effect of the abrasive within the mixture. In general, powders are more abrasive than pastes, and products that claim to be tooth whiteners often are harsher than others. Specific abrasive ingredients which may harm dentin include calcium carbonate, anhydrous dibasic calcium phosphate and silica." See Col. 1, line 57 to Col. 2, line 3. (Emphasis added).

Parran et al disclose oral compositions containing soluble pyrophosphate salts which provide an anticalculus (aka tartar) benefit (see abstract) in the amount of at least 1.5 % in addition to "from about 0% to about 70% of a dental abrasive selected from the group consisting silica, alumina, calcium pyrophosphate, insoluble metaphosphates and thermosetting polymerized resins". See Col. 2, lines 36-55. Thus, the Examiner's characterization that 1.5% of anticalculus amount "is encompassed by the claimed 1 % to about 4%" is ignoring the teaching of the reference that this 1.5% amount is an at least about amount of the tartar benefit portion, in addition to "from about 0% to about 70% of a dental abrasive selected from the group consisting silica, alumina, calcium pyrophosphate, insoluble metaphosphates and thermosetting polymerized resins" noted above. (Emphasis added) Since the 1.5% mentioned in Parran relates to $P_2O_7^{-4}$, the tartar benefit amount, and not to the amount of the anticalculus compounds themselves, and Parran also specifically discloses "an amount of a soluble pyrophosphate salt selected from the group consisting of dialkali metal and mixtures of dialkali metal and tetraalkali metal pyrophosphate salts sufficient to provide at least about 1.5% $P_2O_7^{-4}$; and … wherein the pH of said

composition is from about 6.0 to about 10.0 and the composition does not contain more than about 4.0 $K_4P_2O_7^{-4}$", the amount of metal phosphate total is necessarily much higher. See Col. 2, lines 45-53. (Emphasis added) This reference, in combination with the teaching in Showa Denko KK, teaches higher amounts of anticaculus compounds.

Pera is only cited by the Examiner to teach strontium as a sensitivity relief agent. Besides, Pera teaches away from the use of normal tartar control agents and abrasives, as noted above.

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142.

Applicant respectfully submits that there is no teaching of a tartar control agent in the amounts of about 1 to about 4% of the composition in combination with an ascorbyl-2-phosphate compound, or a sodium or potassium salt thereof, "wherein the compound displays adhesion to oral tissue or tooth for at least five minutes" in Showa Denko KK alone or in combination with the other two references, even if it is combinable, since Pera also specifically teaches away from a phosphate tartar control agent.

As for the article of http://pubs.acs.org/hotartcl/chemtech/95/dec/dec.html December 1995 cited by the Examiner, it discloses "wherein it is recited that Sodium fluoride, sodium monofluorophosphate, and stannous fluoride are the most common fluoride sources used in toothpaste. Great care must be taken in the formulation of these agents so that their anticaries activity is not reduced by other dentifrice ingredients, such as the abrasive system. For example, whereas

sodium monofluorophosphate is compatible with both silica and dicalcium phosphate dihydrate abrasives, sodium fluoride is most compatible with the silica abrasive at neutral pH values….". The Examiner's contention that because the article discloses neutral pH, "it would have been obvious to employ a pH of 5.5 to 10 since this range encompasses neutral pH's and this would be most compatible for formulations with fluoride" is not tenable. The reference specifically teaches that a neutral pH is compatible and citing difficulties involved when other pH range is used, not just with abrasives, but other usual ingredients of a dentifrice. The present invention teaches acidic as well as basic pH. Teaching away from acidic and basic pH is not sufficient to establish a *prima facie* case of obviousness.

Also, amended claim 1 no longer recites a pH limitation. This rejection is now moot.

The deletion of the pH range from claim 1 broadens the claim. Therefore, this subject amendment should not narrow the available scope of equivalents under the Doctrine of Equivalents, as noted above.

Therefore, claim 1 is patentable over Show Denko KK JP 62096408 in view of of Pera U.S. Patent No. 4,755,525 and Parran et al. U.S. Patent No. 4684518.

As for claims 55 and 64, Applicant respectfully submits that none of the cited references, alone or in combination, teaches the subject matter of claim 55 or 64, and they are also patentable for at least the same reasons as noted above for claim 1.

In response to Applicant's arguments, the Examiner notes that claim 55 is drawn to the inclusion in the composition of "an ingredient promoting the adherence of the composition to the tooth or tissue, not an "adhesion promoting agent", and that "it is not stated how long the composition will remain on the

tooth", "since a thickener would help the composition remain on the tooth during brushing, it fits the claim." Applicant wishes to point out that the argument made in relationship to an "adhesion promoting agent" also applies to "an ingredient promoting the adherence of the composition to the tooth or tissue". Also, the arguments advanced by the Examiner concerning a toothpaste during brushing in now moot.

Therefore, claims 1, 55 and 64 are patentable over Show Denko KK JP 62096408 in view of Pera U.S. Patent No. 4,755,525 and Parran et al. U.S. Patent No. 4684518.

Claims 2-5, 7, 11-12, 16-35, 37-39, 41-43, 45- 46, and 56-60 are dependent from claims 1 and 55, respectfully and are also rejected under 35 U.S.C. 103(a) as being unpatentable over Showa Denko KK in view of Pera and Parran. While Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that this rejection is moot in view of the remarks made in connection with independent claims 1, and 55. The dependent claims include all of the limitation of the base claims and any intervening claims, and recite additional features which further distinguish them from the cited references. Therefore, dependent claims 2-5, 7, 11, 12, 16-35, 37-39, 41-43, 45, 46 and 56-60 are also in condition for allowance.

Applicant respectfully submits that claims 65-66 are also in condition for allowance for at least the same reasons as noted for claim 64.

Applicant respectfully requests that the rejection of claims 1-5, 7, 11, 12, 16-35, 37-39, 41-43, 45,46 and 55-60 under 35 U. S.C. 103(a) as being unpatentable over Show Denko KK JP 62096408 in view of Pera U.S. Patent No. 4,755,525 and Parran et al. U.S. Patent No. 4684518 be withdrawn. Reconsideration is respectfully requested.

II. Priority Claim

Applicant claims a pH of the composition from about 5.5 to about 10.0 now in independent claim 1. However, if applicant wishes to rely on provisional application number 60/263884, for a priority date of 1/24/01, the only pH present in the priority document is a teaching of a pH of 8.86 in one specific formulation. There is no recitation of a pH of from about 5.5 to about 10.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S. C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). The disclosure of the prior-filed application, Application No. 60/263884, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. For the purpose of search and examination, the priority date for claims 1-5, 7, 11, 12, 17-35, 37-37, 41-43, 45 and 46 is determined to be January 24, 2002.

Applicant respectfully traverses the rejection.

In Wertheim, the court held that a disclosure of "solids contents within the range of 25-60% along with specific embodiments of 36% and 50%" supports a claimed range of "35-60%" even though there is no literal language to support it in the disclosure". *In re Wertheim, 541 F.2d 257, 265 191 USPQ 90 (CCPA 1976).*

Here, Applicant respectfully submits that a composition having a pH range is fully disclosed by the table on page 3 of the provisional application. The

table depicts a range of ingredients with % ranges. The pH range, which, though not explicitly disclosed in the provisional, is inherently present in the examples shown. The range can actually both be calculated or measured. For example, sodium ascorbyl phosphate has a pH of 9-10 at a 3% solution. See ttp://www.sciencelab.com/page/S/PVAR/10426/SLS3580. A 0.4 M solution (1.68%) of sodium fluoride (molecular weight of 42) has a pH 3 to 4. See http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=243760. Based on these known values, it can be seen that the pH range of the formulations in the table of page 3 of the provisional is about 5.5 to about 10. In addition, Applicant also previously submitted a 37CFR 1.132 declaration after discussion with the Examiner at the interview, to show the pH range of actual formulations made in accordance with the ingredient list presented on page 3 of the provisional application. Thus, the pH range merely represents the inherent values of the formulations.

Reconsideration is respectfully requested.

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CONCLUSION

In view of the remarks provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims: 1-5, 7, 11-12, 16-35, 37-39, 41-43, 45-46, 55-60, and 64-66.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact the undersigned at 310-621-6415.

Dated: February 6, 2009

Respectfully submitted,

/Nancy N. Quan/

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